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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,168

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Karl Mulligan

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8905

23973

7590

06/08/2009

DRINKER BIDDLE & REATH

ATTN: INTELLECTUAL PROPERTY GROUP

ONE LOGAN SQUARE

18TH AND CHERRY STREETS

PHILADELPHIA, PA 19103-6996

EXAMINER

DUFFY, BRADLEY

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

06/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,168

Applicant(s)

MULLIGAN ET AL.

Examiner

BRADLEY DUFFY

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/19/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 23-26, 28, 29, 31 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 19, 28, 29 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 18 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2006 and 11/14/08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Exhibit A

DETAILED ACTION

1. The amendment filed February 19, 2009, is acknowledged and has been entered. Claims 18, 23 and 25 have been amended.
2. Claims 18, 19, 23-26, 28, 29, 31 and 39 are pending in the application.
3. Claims 19, 28, 29 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed March 7, 2008.
4. Claims 18, 23-26 and 39 are under examination.
5. The supplemental statement of biological deposit filed November 14, 2008, is acknowledged and has been entered. The needed assurances required by 37 CFR 1.801-1.809 have been met for the hybridoma cell line deposited as ECACC Deposit No. 03073001 in view of this statement, and the statement of biological deposit that was filed 12/7/2006 for the hybridoma cell line deposited as ECACC Deposit No. 03073001.

Grounds of Objection and Rejection Withdrawn

6. Unless specifically reiterated below, Applicant's amendment and/or arguments filed November 14, 2008, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed June 11, 2008.

Grounds of Objection Maintained

Specification

7. The disclosure is objected to for the following reasons:
The objection to the specification, because the disclosure refers to embedded

hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified, is maintained. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

Applicant has submitted at page 12 of the response filed November 14, 2008, that the information of the websites referred to at pages 16 and 17 is not improperly incorporated because, "To comprise an incorporation by reference, the words "incorporated by reference" or the like must be utilized. "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U. S.C. 112, first paragraph." MPEP608.01(p)I.A. (citing *In re De Seversky*, 474 F.2d 671,177 USPQ 144 (CCPA 1973)".

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The argument is not found persuasive because while the term "incorporated by reference" is not expressly used, it is submitted that the specification sets forth that the protocols being referred to at these sites is part of the disclosure because e.g., it refers to synthesizing cDNA by the **protocol** set forth at the Stratagene website at page 17 in the following disclosure:

This was performed using a Stratagene cDNA synthesis kit (following their protocol). Stratagene ZAP EXPRESS cDNA Synthesis Kit Instruction Manual [www<dot>stratagene<dot> com/manuals/200403<dot>pdf](http://www.stratagene.com/manuals/200403.pdf).

Accordingly, it is submitted that while the phrase "incorporated by reference" is not expressly present, referring to these websites is not a "mere reference to another ... publication", but refers to protocols and guidelines that are part of the disclosure.

As set forth in the previous office action, it is impermissible that a patent's disclosure incorporate essential or non-essential material by reference to, for example, embedded hyperlinks and/or other forms of browser-executable code, because the information contained in the websites or databases to which the hyperlinks or other

forms of browser-executable code connect **may not be maintained** on the Internet for the duration of the patent's term and **may not contain** the same information after the filing date of an application that was contained in the website or database on or before the filing date of the application. Since the information contained in a website may vary, it is not evident that information contained in a website will always remain useful to the practitioner or even applicable to the invention; and information contained in an extinct website cannot possibly be helpful to the practitioner. Furthermore, the validity of a patent containing a reference to a hyperlink or other form of browser-executable code may be reasonably questioned if the website(s) to which the hyperlink(s) connect were relied upon by the patentee(s) to provide sufficient disclosure or description of the invention to meet the requirements of 35 USC § 112, first and second paragraphs. As such, recitation of such references is not permitted. Notably, e.g., the PDF being referred to at [www<dot>stratagene<dot> com/manuals/200403<dot>pdf](http://www.stratagene.com/manuals/200403.pdf) currently has a copyright date of 2008 (see attached Exhibit A), while the instant application claims priority to November 14, 2003, so it is immediately apparent that the websites being referred to **may not contain** the same information after the filing date of an application that was contained in the website or database on or before the filing date of the application.

Accordingly, it is maintained that the reference to the guidelines and protocols at these websites, is considered to be an improper incorporation by reference and is not permitted. See 37 CFR 1.57(d) and MPEP § 608.01(p).

Appropriate correction is required.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 18 and 23-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained.

At page 13 of the amendment filed November 14, 2008, Applicant has traversed this ground of rejection submitting that this rejection has been obviated by the amendment to claim 18.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

In this case, while claim 18 has been amended to recite "a monoclonal antibody *produced* from a hybridoma cell", the rejection has not been obviated because it is also unclear what is a monoclonal antibody *produced from* a hybridoma cell? Is it an antibody produced by the hybridoma, an antibody cloned from the hybridoma, an antibody produced by immunizing a host with an antigen expressed by the hybridoma, an antibody produced by expressing an antibody expression construct in the hybridoma, and antibody somehow derived from the antibody produced by the hybridoma or is the antibody *produced from* the hybridoma cell in some other way? Therefore, it is submitted that the metes and bounds of the subject matter that is regarded as the invention is not delineated with the clarity and particularity to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, so as permit the skilled artisan to know or determine infringing subject matter.

If Applicant regards their invention as the monoclonal antibody *produced* by the hybridoma deposited as ECACC No. 03073001, it is suggested that this issue could be remedied by amending the claim to recite, e.g., "The monoclonal antibody *produced* by the hybridoma cell of claim 39".

Accordingly, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The rejection of claims 18 and 23-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

Starting at page 13 of the amendment filed November 14, 2008, Applicant has traversed this ground of rejection first submitting that this rejection has been obviated by the amendment to claim 18.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

Again, the considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

In the instant case, as amended, the claims are broadly drawn to a structurally and functionally diverse genus of "monoclonal antibodies *produced from* a hybridoma cell of ECACC Deposit No.03073001" or an antigen binding fragment thereof.

In this case, it appears that Applicant is submitting that the amendment to recite "produced" as opposed to "obtainable" has obviated this rejection, but this is not found persuasive because the claims recite "produced from" as opposed to "produced by". As set forth in the previous office action, in this case, the written description only adequately describes the monoclonal antibody *produced by* the hybridoma cell line deposited as ECACC Deposit No. 03073001 and antigen-binding fragments of said

monoclonal antibody (see page 4, lines 1-11, page 12, line 28 to page 13, line 29 and page 17, line 16 to page 18, line 1).

For example, as set forth in the previous action, methods of recombinant expression of monoclonal antibodies are well-known in the art and hybridoma cells are capable of expressing functional antibodies (see e.g., Antibody Engineering: A Practical Approach, (Edited by McCafferty et al, Oxford University Press: pages 282 and 283, 1996, of record). Accordingly, one of skill in the art could reasonably produce from a hybridoma cell of ECACC Deposit No.03073001 any monoclonal antibody that has been cloned by recombinant DNA methods by expressing it in a hybridoma cell of ECACC Deposit No.03073001. For example, Shearman et al (J. Immun., 147(12):4366-4373, 1991) teach a humanized monoclonal antibody that has been cloned into mammalian expression vectors and transfected into a murine hybridoma cell line and expressed in that cell line. Shearman et al further teach that this monoclonal antibody has specificity for the human $\alpha\beta$ TCR antigen (see entire document, e.g., abstract and page 4367). Therefore, because the humanized monoclonal antibody of Shearman et al can be expressed in murine hybridoma cells, such as a hybridoma cell of ECACC Deposit No.03073001, this monoclonal antibody is reasonably considered an antibody that could be *produced* from a hybridoma cell of ECACC Deposit No.03073001. Notably, the humanized monoclonal antibody of Sherman et al binds a completely distinct antigen than the monoclonal antibody *produced* by the hybridoma cell line deposited as ECACC Deposit No.03073001, the only particularly described "antibody", which is a member of this broad genus of "monoclonal antibodies *produced* from a hybridoma cell of ECACC Deposit No.03073001". Accordingly, because "monoclonal antibodies *produced* from a hybridoma cell of ECACC Deposit No.03073001", need not bind any particular antigen, one of skill in the art would not recognize that the monoclonal antibody *produced* by the hybridoma cell line deposited as ECACC Deposit No.03073001 was representative of any other antibodies in this genus which bind to such structurally and functionally diverse antigens. For these reasons, one of skill in the art would not recognize that Applicant was in possession of the structurally and functionally diverse genus of

"monoclonal antibodies *produced* from a hybridoma cell of ECACC Deposit No.03073001".

Secondly, with regard to the "biological targeting devices" of claim 26, Applicant has argued that Claim 26 has adequate written description because, "The skilled person would immediately understand claim 26 to be directed to a device wherein the specific antibody of claim 18 or an antigen binding fragment thereof can target a therapeutic ligand (a compound which can be used to provide a therapeutic effect), for example a therapeutic ligand suitable for radiotherapy" and further cites a review by McCarron et al to establish that antibody conjugates were known in the art.

In response, the claims are not limited to an antibody conjugate as set forth by McCarron et al and as argued by Applicant. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As set forth in the previous action, the specification does not provide any guidance that sets forth any particularly identifying structural feature that this genus of "biological targeting devices" would necessarily have and the specification does not expressly limit a "targeting device" to an antibody. Furthermore, the claims do not require the "targeting device" to be an antibody and therefore there can be no correlation of any particular identifying structural feature with any function of the claimed "biological targeting devices". Accordingly, while Applicant's arguments that the broad genus of "biological targeting devices" is adequately described have been fully and carefully considered, they were not found persuasive.

Therefore, after careful and complete consideration of Applicant's arguments, for these reasons and as explained more fully in the Office action mailed June 11, 2008, the specification as filed would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed and this rejection is maintained.

12. The rejection of Claims 18 and 23-26 rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making and using** any antibodies encompassed by the claims, which have been described by the prior art, **does not reasonably provide enablement for making and using** the claimed monoclonal antibodies *produced from* a hybridoma cell of ECACC Deposit No.03073001, diagnostic kits for diagnosing the presence of a cell selected from the group consisting of astrocytoma cells, malignant melanoma secondary tumor cells and primary breast carcinoma cells or biological targeting devices, is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Again, there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

The amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to enable the skilled artisan to make and/or use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

At page 13 of the amendment filed November 14, 2008, Applicant has first submitted that this rejection has been obviated by the amendment to claim 18.

In response, this argument is not found persuasive regarding "monoclonal antibodies *produced* from a hybridoma cell of ECACC Deposit No.03073001" because as set forth in the above rejection of the claims as lacking adequate written description, "monoclonal antibodies *produced* from a hybridoma cell of ECACC Deposit No.03073001" are inclusive of antibodies that need not bind any particular antigen and include any antibodies that could be *produce* from a hybridoma cell of ECACC Deposit No. 03073001, such as recombinant antibodies that are unrelated to the monoclonal antibody *produced* by the hybridoma of ECACC Deposit No. 03073001. Accordingly, it is submitted that one of skill in the art would be subject to undue and unreasonable experimentation to make and use antibodies commensurate in scope with the claimed invention, because the specification does not provide any specific, non-general guidance as to which antibodies could be produced from a hybridoma cell of ECACC Deposit No. 03073001.

Secondly, with respect to Claim 26 Applicant appears to be arguing that the "biological targeting devices" are enabled because one of skill in the art could make antibody conjugated to therapeutic ligands.

In response, as set forth above the claims are not limited to an antibody conjugate as argued by Applicant, but broadly encompass any "targeting device". Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the "targeting device", it is noted that the specification does not provide any specific non-general guidance that sets forth any particularly identifying structural and/or functional features that this genus of biological targeting devices would necessarily have. For this reason, one of skill in the art would be subject to undue experimentation to make and use the claimed "biological targeting devices" which could comprise any structural and/or functional features because they would have to unduly and unreasonably experiment to determine which "biological targeting devices" comprising the recited

features could be made and then subject to further undue experimentation to determine a use for these "devices".

Finally, with respect to claims 23-25, Applicant appears to be arguing that diagnostic kits comprising a primary antibody according to claim 18 with the intended use for diagnosing the presence of a cell selected from astrocytoma cells, malignant melanoma secondary tumor cells and primary breast carcinoma cells, are enabled because one could identify astrocytoma cells, malignant melanoma secondary tumor cells and primary breast carcinoma cells in a tissue of known origin.

In response, the claims do not recite an intended use for diagnosing the presence of a cell selected from astrocytoma cells, malignant melanoma secondary tumor cells and primary breast carcinoma cells in a tissue sample of known origin and as set forth above, limitations are not read in to the claims.

Furthermore, as set forth in the previous office action Li et al (Nature Gen., 16:243-251, 1997, IDS filed 1/17/2007) teach that human Jagged1 is expressed in various adult human tissues, including stomach, thyroid gland, spinal cord, lymph node, trachea, adrenal gland and bone marrow (see entire document, e.g., page 244). Accordingly, the MQ1 antibody *produced* by the hybridoma cell line deposited as ECACC Deposit No. 03073001 would bind to multiple other cell types which normally express the human Jagged1 polypeptide and one of skill in the art could not distinguish whether a cell was an astrocytoma cell, a malignant melanoma secondary tumor cell or a primary breast carcinoma cell using the claimed diagnostic kit because the antigen recognized by the monoclonal antibody *produced* by the hybridoma cell line deposited as ECACC Deposit No. 03073001 is expressed in multiple different cell types. In this case, as set forth in the previous office action, it is the intended use of the claimed kits that one of skill in the art would be subject to undue experimentation to use, so it is suggested that this part of the rejection could be obviated by amending to claim to recite "A composition comprising the monoclonal antibody *produced by* the hybridoma cell of claim 39, or an antigen-binding fragment thereof", for example.

Accordingly, for these reasons and as set forth in the Office action mailed June

11, 2008 the specification as filed does not reasonably enable one of skill in the art to make and/or use the full scope of the claimed antibodies, biological targeting devices and kits without undue and/or unreasonable experimentation. Thus, while Applicant's arguments traversing this ground of rejection have been fully and carefully considered, they were not found persuasive as the amount of guidance, direction, and exemplification in the specification is not sufficient to reasonably enable the skilled artisan to make and/or use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The rejection of claims 18, 23, 24 and 26 under 35 U.S.C. 102(b) as being anticipated by Shearman et al (J. Immun., 147(12):4366-4373, 1991), is maintained.

At page 18 of the amendment filed November 14, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

Applicant has argued that Shearman et al does not teach "[t]he monoclonal antibody produced by the hybridoma ECACC 03073001"

In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g., "[t]he monoclonal antibody produced by the hybridoma ECACC 03073001") are not recited in the rejected claim(s). Notably, claim 18 recites a monoclonal antibody *produced from a hybridoma cell of ECACC Deposit No. 03073001*, and as set forth in

the above rejection of the claims under 35 USC 112, first paragraph, since the monoclonal antibody of Shearman et al is reasonably considered an antibody that could be *produced* from a hybridoma cell of ECACC Deposit No. 03073001, the monoclonal antibody and compositions comprising said monoclonal antibody of the prior art remain materially and structurally indistinguishable from the instantly claimed monoclonal antibody and compositions.

Therefore, after careful and complete consideration of Applicant's response, for these reasons and the reasons of record as explained in the preceding Office action, Shearman et al still anticipates the instant claims and this rejection is maintained.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. The rejection of claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shearman et al (J. Immun., 147(12):4366-4373, 1991) in view of Monia et al (US Patent 6,020,199, February 1,2000), is maintained.

At page 18 of the amendment filed November 14, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

In response, as set forth in the above 102(b) rejection, since the monoclonal antibody of Shearman et al is reasonably considered an antibody that could be *produced* from a hybridoma cell of ECACC Deposit No. 03073001, it is being maintained that it would be obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition comprising an antibody specific for human α/β TCR antigen as taught by Shearman et al and at least one labeled secondary antibody that binds this antibody to monitor binding of the Shearman et al antibody to the human α/β TCR antigen by any immunoassay technique and that such composition and it is submitted that such compositions remain encompassed by the scope of claims 23 and 25.

Therefore, after careful and complete consideration of Applicant's response, for these reasons and the reasons of record as explained in the preceding Office action, Shearman et al view of Monia et al still renders the instant claims obvious and this rejection is maintained.

Conclusion

18. Claim 39 is allowed. No other claims are allowed.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liao et al (Antican. Res., 21:1673-1680, 2001) teach the DNA cloning of an scFv monoclonal antibody linked to IL-2 and expressing this monoclonal antibody in hybridoma cells.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
June 4, 2008